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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,984	05/23/2000	Daniel H. Macs	2870/287	1797

7590 01/15/2008
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EXAMINER

PRYOR, ALTON NATHANIEL

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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01/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/554,984

Applicant(s)

MAES ET AL.

Examiner

Alton N. Pryor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,6,8-13,15-26,28,33 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,6,8-13,15-26,28,33,35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/21/07
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's arguments filed 7/26/07 have been fully considered but they are not persuasive. See argument below.

I. Applicant argues that Simon does not make obvious specific combination of ingredients, i.e. a composition comprising 0.1 to 10% actives selected from Asiatic acid, dihydroxacetone, essential oils, essential fatty acids and vitamin D derivatives. Examiner disagrees with Applicant since the ingredients of the composition are common to the cosmetic art. See argument below. Applicant makes mention of unexpected results for the instant invention on page 9 lines 23-34 and page 10 lines 1-8. However, the statement is not accompanied with actual data for the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4,6,8-13,15-26,28,33,35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon et al (USPN 5932234), Bissett et al (USPN 6183761), Elias et al (USPN 5885565) and Subbiah (USPN 6150381). Simon teaches a skin care composition comprising a cosmetic and / or dermatological active agent for treating a variety of skin conditions such as aging and acne. Simon teaches that the active comprises 0.1 to 10% of the skin care composition and can be selected from a number of ingredients including Asiatic acid, dihydroxacetone, essential oils, essential fatty

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acids and vitamin D derivatives. See column 5 line 49 – column 5 line 38. Simon suggests that the composition can comprise of one or more actives. See column 5 lines 49 – 65. Note Simon is open to the inclusion of many more actives since Simon recites in column 5 lines 66-67 “Among the actives which may be used in the present invention, mention may be, for example of:” The phrase “may be, for example” allows for the addition of other actives besides those mentioned in the specification to his composition / process. Simon also teaches that other ingredients such as sunscreens can be added to the skin care composition. See column 5 lines 44-48. Simon teaches a method of applying the composition to the skin in order to treat skin related disorders such as aging and acne. Simon does not teach the invention comprising 1) betunlinic acid or boswellic acid, 2) cholesteryl sulfate, and 3) sclareolide.

Bissett teaches a skin care or skin regulating composition comprising betunlinic acid or boswellic acid. See abstract, claim 1. Bissett teaches a method of applying the composition to the skin in order to treat aging, dry skin, and skin conditions cause by microorganisms (acne). See column 3 line 26 – column 5 line 21. It would have been obvious to one having ordinary skill in the art to modify the invention of Simon to include boswellic acid or betunlinic acid. One would have been motivated to do this since Simon allows for the inclusion of other compounds (actives) in his invention. Additionally, one would have been motivated to do this because boswellic acid and betunlinic acid are used extensively in the skin care / cosmetic art. The modified Simon-Bissett invention does not include sclareolide.

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Subbiah teaches a skin care or cosmetic composition comprising sclareolide. See abstract, claim 1. Subbiah teaches a method of applying the composition to the skin to treat a skin condition such as acne. See column 2 line 55 - column 3 line 41. It would have been obvious to one having ordinary skill in the art to modify the invention of Simon-Bissett to include sclareolide. One would have been motivated to do this since Simon allows for the inclusion of other compounds (actives) in his invention. Additionally, one would have been motivated to do this because sclareolide is used extensively skin care / cosmetic art. The modified Simon-Bissett-Subbiah invention does not include cholesterol sulfate.

Elias teaches a method of enhancing the penetration of an active into the skin using a sterol such as cholesterol sterol. See abstract. Elias teaches a method of combining the sterol with an active and then applying the combination to the skin. See claim 1. The cholesterol sterol, which is hydrophobic, enhances the transport of the active compound through the skin. One having ordinary skill in the art would have been expected to modify the combined invention of Simon-Bissett-Subbiah to include cholesterol sulfate. One would have been motivated to do this in order to make an invention with enhanced permeability of the actives through the skin.

Response to Applicant's argument

Applicant argues:

- 1) When the prior art suggests numerous possible choices, the prior art constitutes at most a suggestion that it would be "obvious to try" each of the numerous possible choices until one possibly arrive at a successful

result, which is insufficient for supporting a prima facie case of obviousness under 35 USC 103.

- 2) The prior art references fail to teach or suggest any specific combination of protease inhibitor(s) with cell differentiation enhancers and the references do not provide any direction or guidance as to which specific combinations of ingredients from the laundry list would be successful in enhancing the skin's natural lipid barrier.
- 3) Examiner ignored that nothing in Simon teaches or suggests the specific combinations of DHA, essential fatty acids, essential oils, Asiatic acid, and vitamin D and thereof as presently claimed.
- 4) Bissett, Elias, and Subbiah like Simon fail to teach or suggest the specific combinations of protease inhibitor(s) and cell differentiation enhancers as presently claimed.

Examiner argues when the prior art recite the components in a list and in addition, disclose one or more of the components can be combined to produce a composition, it would have been "obvious to try" all possible combinations regardless of the size of the list. (Recent KSR decision). In the absence of unexpected data, all possible combinations of ingredients would have been expected to be successful since the prior art suggests the ingredients and since the prior art suggest that combinations of the ingredients can be made. In such an instance, the references do not have to provide any direction or guidance as to which combinations would be successful. The fact that the references suggest the mixture(s) / combination(s) makes its obvious to

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expect that the mixture(s) / combination(s) would be successful. Note a reference is not required to recite all possible combinations in order to render an invention obvious.

Applicant does not provide any unexpected data for the specifically claimed combinations positively recited in the claims that would possibly remove this rejection.

For this reason, the 35 USC 103(a) obviousness rejection over Simon, Bissett, Elias, and Subbiah is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

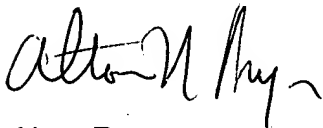
Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Alton Pryor
Primary Examiner
AU 1616